

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Addiese: COMMISSIONER FOR PATENTS P O Box 1430 Alexandra, Virginia 22313-1450 www.wepto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
10/673,351	09/30/2003	Sean J. Hart	NC 84,517	8470
20384 7590 0325/2008 NAVAL RESEARCH LABORATORY ASSOCIATE COUNSEL (PATENTS) CODE 1008.2 4555 OVERLOOK AVENUE, S.W. WASHINGTON, DC 20375-5320			EXAMINER	
			DRODGE, JOSEPH W	
			ART UNIT	PAPER NUMBER
			1797	
			MAIL DATE	DELIVERY MODE
			03/25/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Application No. Applicant(s) 10/673,351 HART ET AL. Office Action Summary Examiner Art Unit Joseph W. Drodge 1797 -- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS. WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). Status 1) Responsive to communication(s) filed on 10 March 2008. 2a) ☐ This action is FINAL. 2b) This action is non-final. 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213. Disposition of Claims 4) Claim(s) 11-18 is/are pending in the application. 4a) Of the above claim(s) _____ is/are withdrawn from consideration. 5) Claim(s) _____ is/are allowed. 6) Claim(s) 11-18 is/are rejected. 7) Claim(s) _____ is/are objected to. 8) Claim(s) _____ are subject to restriction and/or election requirement. Application Papers 9) The specification is objected to by the Examiner. 10) The drawing(s) filed on is/are; a) accepted or b) objected to by the Examiner. Applicant may not request that any objection to the drawing(s) be held in abevance. See 37 CFR 1.85(a). Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received.

1) Notice of References Cited (PTO-892)

Notice of Draftsperson's Patent Drawing Review (PTO-948)

Information Disclosure Statement(s) (FTO/S5/08)
Paper No(s)/Mail Date _______.

Attachment(s)

Interview Summary (PTO-413)
Paper No(s)/Mail Date.

6) Other:

5 Notice of Informal Patent Application

Art Unit: 1700

The indicated allowability of claims 11-18, as indicated by the Board of Patent Appeals and Interferences is withdrawn in view of the newly discovered reference(s) to Nishimura et al patent 5,495,105 (originally applied against originally filed claims 1-10) in combination with Dapprich patent 6,585,939 (applied against the claims in the Final Rejection of 22 March 2006). Rejections based on the newly cited reference(s) follow.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- Determining the scope and contents of the prior art.
- Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Application/Control Number: 10/673,351 Page 3

Art Unit: 1700

Claims 11-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nishimura et al patent 5,495,105 (originally applied against originally filed claims 1-10) in view of Dapprich patent 6,585,939 (applied against the claims in the Final Rejection of 22 March 2006).

Nishimura teach a microfabricated/miniaturized device for performing biological testing of samples containing DNA particle material (column 1, lines 15-27 and column 2, lines 28-38), by manipulating flow of the particles by directing light travel from laser sources 5 and lense input parts 6 (column 1, lines 52-62) in an opposite direction to the flow of fluid through a fluid pathway (figure 2 and column 2, lines 1-10). The fluid pathways of Nishimura are also miniaturized to the approximate diameters of the DNA particles (column 47-51). The body containing the fluid pathways of the Nishimura device is comprised of glass or plastic (column 2, lines 39-40 and column 5, lines 55-57).

Application/Control Number: 10/673,351 Page 4

Art Unit: 1700

Independent claims 11 and 17 and dependent claims 12,14 and 18 all differ in requiring the flow-path containing body to comprise polydimethylsiloxane (PDMS). However, Dapprich teaches a body for performing assays of DNA advantageously employing PDMS instead of materials limited to glass and plastic (column 3, lines 14-51 and column 4, lines 1-21). An array of advantages of the PDMS material are discussed at column 3, lines 33-42 pertaining to durable construction and biocompatible and optical and chemical properties of the material. The body includes flow paths of directed fluid flow (column 11, line 15-column 12, line 20) and light input sources including lasers and light input parts including lenses and other light manipulating devices (column 5, lines 17-28 and column 12, line 22-column 13, line 15). It would have been obvious to one of ordinary skill in the art to have utilized the PDMS material of Dapprich in the device of Nishimura, because of the biocompatible, chemical and optical properties of the material as well as it's cheap and durable construction.

Art Unit: 1700

Claims 13-16 differ from Nishimura in requiring the body to comprise a 1st material that has the fluid pathway and the light imput part to comprise a second material. However, Dapprich teaches light input parts to comprise varied materials for their superior optical properties (see column 12, lines 31-43 concerning lens components of epoxy or other resin materials and see column 8, lines 30-35 concerning dye materials applied to selected surfaces for their optical propeties). It would have been obvious to one of ordinary skill in the art to have utilized a different material for the light input part of the body of Nishimura than for the fluid pathway part of the body of Nishimura, as taught by Dapprich because of the optical properties of the different materials pertaining to light absorbing, scattering, focusing and/or polarities.

For claims 12, 16 and 18, different one of the lens system 6 of the Nishimura system and the surface of the flow channel facing the lens system can variously be considered components of light inputting part and light manipulating part.

For claim 14 and recitation of PDMS material, see discussion of claim 11.

For claim 15, both Nishimura (column 2, line 40) and Dapprich column 4, line 33) discuss glass components.

Art Unit: 1700

Claims 11-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dapprich patent 6,585,939 (applied against the claims in the Final Rejection of 22 March 2006) in view of Nishimura et al patent 5,495,105 (originally applied against originally filed claims 1-10).

Dapprich discloses a poly-dimethylsiloxane (PDMS) body 11 containing flow-through fluid pathways 64,66, primarily comprised of PDMS plastic (column 7, line 66-column 8, line 11 and column 10, lines 2-15) as required by independent claims 11 and 17 and dependent claim 14; the fluid pathways arranged to permit/facilitate flow in first discrete directions therethrough such as by peristaltic and other pumping components and other pressure-applying components (column 11, line 49-column 12, line 20).

and light input part (lenses 60 or 62 or described in column 12, lines 31-53 and column 12, line 58-column 13, line 15; also column 13, lines 19-28 and lines 33-35) that may be comprised of, or contain different material(s) than PDMS such as epoxy or other resins, additives or metallized layers, as required by independent claim 13, or have dye surfaces as at column 8, lines 30-35 with specific optical properties.

Art Unit: 1700

For all claims, Dapprich also disclose use of the microstructures for performing biological assays and reactions, especially with regard to DNA and other polynucleotides (Abstract, column 4, lines 36-67). Light sources may encompass various lasers to optically excite the samples (column 5, lines 17-28).

All of the claims differ from Dapprich in requiring the light input part being arranged to manipulate travel of light in a 2nd direction that is opposite the 1st direction of the fluid flow through a pathway. However, Nishimura teach a device for performing biological testing of samples containing DNA particle material (column 1, lines 15-27 and column 2,lines 28-38), by manipulating flow of the particles by directing light travel from laser sources 5 and lense input parts 6 (column 1, lines 52-62) in an opposite direction to the flow of fluid through a fluid pathway (figure 2 and column 2, lines 1-10). The fluid pathways of Nishimura are also miniaturized to the approximate diameters of the DNA particles (column 47-51) and are in a body comprised of glass or plastic (column 2, lines 39-40 and column 5, lines 55-57.

Art Unit: 1700

It would have been obvious to one of ordinary skill in the art to have arranged one or more of the light sources and light input parts of the Dapprich device to accept and direct light travel in the opposite direction of fluid flow travel, as taught by Nishimura, so as to facilitate selective particle trapping and separation, in the assaying of the DNA material

For claims 12, 16 and 18 light manipulating, re-directing or focusing parts, such as additional lenses, as well as mirrors, holographic components, light-guides and other optical scatterers, are disclosed at column 12, lines 22-26 and 44-65 and column 13, lines 15-23).

For claim 15, the light input part may comprise a glass layer (column 9, lines 18-20; column 10, lines 13-15, etc.).

For claims 17 and 18, also see light source 68,70, etc. (column 11, lines 43-48 and column 12, lines 53-58. column 13, lines 20-44, etc.).

Application/Control Number: 10/673,351 Page 9

Art Unit: 1700

Applicant's arguments; arguments presented in the Appeal Brief and Arguments presented on 13 February 2006 and 12 June 2006 against Nishimura and Dapprich taken alone, respectively, with respect to claims 11-18, have been considered but are moot in view of the new ground(s) of rejection. Dapprich clearly disclose/teach PDMS material and use of different materials for the components, while Nishimura clearly disclose/teach arrangement of light source, and light input and manipulating parts to permit and direct light travel in an opposite direction to fluid flow travel. None of the Arguments or Appeal Brief of record in the prosecution has contested or disputed either of these specific issues.

Art Unit: 1700

Any inquiry concerning this communication or earlier communications from

the examiner should be directed to Joseph Drodge at telephone number

 $571\mbox{-}272\mbox{-}1140.$ The examiner can normally be reached on Monday-Friday from

8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the

examiner's supervisor, David Roy Sample, can reached at 571-272-1376. The fax

phone number for the examining group where this application is assigned is

571-273-8300.

Information regarding the status of an application may be obtained from

the Patent Application Information Retrieval (PAIR) system. Status information

for published applications may be obtained from either private PAIR or Public

PAIR, and through Private PAIR only for unpublished applications. For more

information about the PAIR system, see http://pair-direct.uspto.gov. Should you

have any questions on access to the Private PAIR system, contact the Electronic

Business Center (EBC) at 866-217-9197 (toll-free).

JWD 3/13/2008

/Joseph W. Drodge/

Primary Examiner, Art Unit 1797

Reopening prosecution after Board decision is approved.

/Gregory L Mills/

Supervisory Patent Examiner, Art Unit 1700